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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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03/18/2004

Erik Buntinx

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5618

1912

7590

02/20/2009

AMSTER, ROTHSTEIN & EBENSTEIN LLP
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EXAMINER

PACKARD, BENJAMIN J

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

02/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,793	Applicant(s) BUNTINX, ERIK	
	Examiner Benjamin Packard	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49,50,54,55,82,92 and 93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49,50,54,55,82,92 and 93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2pgs (11/7/08)</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 11/07/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 49 and 50 were rejected under 35 U.S.C. 103(a) as being unpatentable over Müller (Expert Opinion on Pharmacotherapy, 2002, Vol. 3, No 4, pp. 381-388) in view of PERMAX® prescribing information (http://www.fda.gov/medwatch/safety/2003/permax_PI.pdf, revised October 2, 2003, pp. 1-2).

This rejection is maintained.

Applicants asserted that removal of separate and sequential limitation overcomes this rejection.

MPEP 2105 states:

Evidence of similar properties or evidence of any useful properties disclosed in the prior art that would be expected to be shared by the claimed invention weighs in favor of a conclusion that the claimed invention would have been obvious. Dillon, 919 F.2d at 697-98, 16 USPQ2d at 1905; In re Wilder, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); In re Linter, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Müller still supports the concept that both drugs can be applied simultaneously. At page 385, Applicants quote Müller as stating “Since classical neuroleptics such as the butyrophenones or phenothiazines increase extrapyramidal symptoms, atypical neuroleptics are primarily used for the treatment of psychotic symptoms in PD.” While applicants previously argued this teaches away from the combination, Examiner interprets it differently. Specifically, Examiner notes that Müller states atypical neuroleptics are “primarily used”, from which one of ordinary skill in the art can reasonably infer that on some occasions, butyrophenones or phenothiazines are used instead of atypical neuroleptics. Such motivation to use a drug with specific side effects may include allergies or interaction with other medications. This disclosure does not state there is adverse effects of combining butyrophenones with pipamperone, but simply one form of neuroleptic is preferred based on the potential of side effects of that compound. Further, Müller implies that any of the disclosed compounds would treat the psychotic symptoms in PD, giving a reasonable expectation of success for using any of the disclosed antipsychotic agents. Where there is no specific teaching against the addition/combination of the butyrophenones, but only a preferential suggestion, it would still be obvious to combine the drugs to produce a combination, regardless if there are more potential side effects.

Claims 54, 55, 92 and 93 were rejected under 35 U.S.C. 103(a) as being unpatentable over Müller (Expert Opinion on Pharmacotherapy, 2002, Vol. 3, No 4, pp. 381-388) in view of Silver et al. (Neurology, 1998, Vol. 50, Suppl. 6, pp. S18-S22).

This rejection is maintained.

Applicants asserted that removal of separate and sequential limitation overcomes this rejection with relation to the Müller reference.

Müller is discussed above.

Where motivation exists in Müller to select butyrophenones or phenothiazines, it would be obvious to co-administer levodopa associated with carbidopa as taught in Silver et al.

Claim 72 were rejected under 35 U.S.C. 103(a) as being unpatentable over Müller (Expert Opinion on Pharmacotherapy, 2002, Vol. 3, No 4, pp. 381-388) in view of Nystrom et al. (US 5,6345,213).

This rejection is maintained.

Applicants asserted that removal of separate and sequential limitation overcomes this rejection with relation to the Müller reference.

Müller is discussed above.

Where motivation exists in Müller to select butyrophenones or phenothiazines, it would be obvious to co-administer levodopa associated with benserazide as taught in Nystrom et al.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612